DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 17, 2017

Medtronic, Inc.
Gayatri Ghadge
Regulatory Affairs Specialist
710 Medtronic Parkway
Minneapolis, MN 55432-5604

Re: K170583
Trade/Device Name: Intersept™ Filtered Cardiotomy Reservoir with Cortiva™ BioActive Surface
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN, DTP
Dated: February 27, 2017
Received: February 28, 2017

Dear Ms. Ghadge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170583

Device Name

Intersept™ Filtered Cardiotomy Reservoir with Cortiva™ BioActive surface

Indications for Use *(Describe)*

The Intersept filtered cardiotomy reservoir with Cortiva bioactive surface is indicated for use in the cardiopulmonary bypass circuit during surgery for:

- an air/fluid separation chamber
- a temporary storage reservoir for priming solution and blood
- the filtration of particulates from bank blood and the storage and filtration of blood recovered from the field by suction
- the addition of medications or other fluids.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: February 27, 2017

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

Contact Person: Gayatri Ghadge
Regulatory Affairs Specialist
Medtronic Perfusion Systems
Phone: 763.526.9336
Fax: 763.367.8361
Email: gayatri.a.ghadge@medtronic.com

Alternate Contacts:
Chelsea Pioske
Senior Regulatory Affairs Supervisor
Medtronic Perfusion Systems
Phone: 763.514.9838
Fax: 763.367.8360
Email: chelsea.pioske@medtronic.com

Jake Roeller
Senior Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: 763.526.0404
Fax: 763.367.8360
Email: jake.w.roeller@medtronic.com

Device Name and Classification

Trade Name: Intersept™ Filtered Cardiotomy Reservoir with Cortiva™ BioActive Surface
Classification Name: Reservoir, Blood, Cardiopulmonary Bypass; Defoamer, Cardiopulmonary Bypass
Regulation Number: 21 CFR 870.4400
Product Classification: Class II
Product Code: DTN, DTP

Name of Predicate Devices: Intersept™ Filtered Cardiotomy Reservoir

Intersept® Filtered Cardiotomy Reservoir with
Medtronic/Carmeda® BioActive Surface

Device Description
The Intersept Filtered Cardiotomy Reservoir with Cortiva BioActive Surface is a single-use, device with a sterile, nonpyrogenic fluid path. The maximum capacity of each reservoir is 2,600 mL. The maximum recommended flow rate is 2 liters per minute (LPM).

Each reservoir has eight luer or 0.6 cm (0.25 in) ID access ports;

- four suction access ports
- two pre-defoamer and
- two post-defoamer access ports. One of the post-defoamer access ports is intended for use as a vent.

Each Intersept Filtered Cardiotomy Reservoir contains an open cell polyurethane defoamer with a 20-micron microaggregate filter covered with a polyester sleeve.

Indications for Use
The Intersept filtered cardiotomy reservoir with Cortiva bioactive surface is indicated for use in the cardiopulmonary bypass circuit during surgery for:

- an air/fluid separation chamber
- a temporary storage reservoir for priming solution and blood
- the filtration of particulates from bank blood and the storage and filtration of blood recovered from the field by suction
- the addition of medications or other fluids

Contraindications

Use the device only as indicated.

Predicate Devices
K926226 Intersept Filtered Cardiotomy Reservoir with Medtronic/Carmeda BioActive Surface
Premarket Notification submission K926226, for the Intersept Cardiotomy Reservoir with filter (model CB1351), was cleared for market by FDA on June 22, 1993. This submission was for the initial introduction of the Intersept Filtered Cardiotomy Reservoir with Carmeda BioActive Surface into the market.

K151110 Intersept Filtered Cardiotomy Reservoir

Premarket Notification submission K151110, for the Intersept Cardiotomy Reservoir with filter (model 1351), was cleared for market by FDA on May 27, 2015. This submission included a proposed alternate material formulation to the inner frames used within the Intersept Filtered Cardiotomy Reservoir, as well as a proposed Instructions for Use/labeling change.

Comparison to Predicate Devices

A comparison of the Intersept Filtered Cardiotomy Reservoir with Cortiva BioActive Surface to the predicate device (the Intersept Cardiotomy Reservoir with Filter and Intersept Filtered Cardiotomy Reservoir with Medtronic/Carmeda BioActive Surface) indicates the following similarities:

- Intended Use: The intended use is the same as predicate device.
- Design: The overall design is the same as the predicate.
- Materials: The material types used are the same as the predicate.
    - The proposed modification in this submission from the predicate device is to an alternate material formulation to the inner frame used within the Intersept Filtered Cardiotomy Reservoir.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance is substantially equivalent to the predicate device.
- Coating: The Cortiva coating is the same as the predicate.
    - The proposed modification in the submission from the predicate device includes: slight alterations to the process steps and solution concentrations of the coating. This includes the alteration to coating process of the defoamer frame assembly inside the reservoir jar; and the filtration sock assembly inside a container.

Summary of Testing

Testing has demonstrated that the Intersept Filtered Cardiotomy Reservoir with Cortiva BioActive Surface is substantially equivalent to the predicate.

The following tests were conducted:

Change	Verification/Validation	Results
Cortiva Coating Process Change	Bioactivity	Pass
	Leaching	Pass
	Coverage	Pass
Alternate Material Formulation Change	Biocompatibility	Pass
	Filtration Efficiency	Pass
	Blood Trauma	Pass

Conclusion

The data included in this submission is sufficient to provide reasonable assurance that the Intersept Filtered Cardiotomy Reservoir with Cortiva BioActive Surface is substantially equivalent to the legally marketed predicate device, the Intersept Filtered Cardiotomy Reservoir with Medtronic/Carmeda BioActive Surface and Intersept Filtered Cardiotomy Reservoir.